

### REMARKS

Claims 11 – 44 are pending in the present application. Claims 11, 30 and 36 are amended and Claim 40 is canceled, leaving Claims 11 – 39 and 41 - 44 for consideration upon entry of the present response. Applicants respectfully request a withdrawal of the rejection and an allowance of the claims based upon the following remarks.

Support for the amendment to Claims 11, 30 and 36 can be found at least in Claim 40.

#### Claims Rejected under 35 U.S.C. § 102

Claims 11- 16, 21, 22, 24 – 31 and 34 – 44 are rejected under 35 U.S.C. §102 (b) as being anticipated by U.S. Patent No. 5,532,217 to Silver et al. (Silver). (Office Action dated 10-03-08, page 2)

In making the rejection, the Examiner has stated that the claims are drawn to a bioactive glass composite comprising biocompatible polymer and a bioactive glass. (Office Action dated 10-03-08, page 2)

In making the rejection, the Examiner has further stated that

[T]he '217 patent teaches a biological composite comprising mineralized fibers, bioactive glass materials and biocompatible polymers (abstract). The claims are drawn to a bioactive glass composite comprising biocompatible polymer and a bioactive glass. The '217 patent teaches a biological composite comprising mineralized fibers, bioactive glass materials and biocompatible polymers (abstract). The bioactive glass comprises a calcium and phosphate molecule (col. 2, lin. 40-49). The biocompatible polymers include gelatin, lanolin, or waxes (col. 2, lin. 50-53). The composite further comprises active agents such as hormones, enzymes and growth factors such as platelet-derived growth factors (col. 2, lin. 57-68). The material is used in bone repair therapies where the material is applied to treat bone defects (abstract, col. 2, lines 5-16). The fibers have the diameter from less than 1 micron to 500 microns (claims). The composite is formed in a method that includes mixing the calcium with phosphate, carrier compounds and extrusion at a temperature of 37 degrees Celsius (example). Regarding the composite at its ability to allow for the proliferation of stem cells, it is the position of the Examiner that these limitations are merely recitations of a future intended use. The claims recite that the "cells when seeded" will proliferate, meaning the composite is not yet seeded and as such any proliferation would be an inherent feature of the composite. The composite of the instant claims

comprises a bioactive glass materials and biocompatible polymers, while the '217 patent teaches an identical composite. Since a compound and its properties cannot be separated, and the composite of the '217 patent is identical to that of the instant claims, it is the position of the Examiner that the composite of the '217 patent would also proliferate any seeded cells.

(Office Action dated 10-03-08, page 2)

To anticipate a claim under 35 U.S.C. § 102, a single source must contain all of the elements of the claim. *Lewmar Marine Inc. v. Barient, Inc.*, 827 F.2d 744, 747, 3 U.S.P.Q.2d 1766, 1768 (Fed. Cir. 1987), *cert. denied*, 484 U.S. 1007 (1988).

Claim 11 as previously amended is directed to a bioactive glass composite, comprising a biocompatible polymer, a bioactive glass including at least one calcium, and at least one phosphorous molecular species; the biocompatible polymer being reacted with the bioactive glass, wherein said calcium and said phosphorous molecular species are not crystalline.

Silver teaches the mineralization of collagen fibers whereby collagen fibers are contacted with a solution of calcium and phosphate ions under conditions to effect nucleation and in-vitro growth of mineral crystals within and on the surface of the collagen fibers to form intact collagen fibers with sub-fibrillar substructure. (see Abstract and see Col. 2, lines 29 - 39) Silver teaches that minerals containing calcium and phosphate are in the form of brushite or hydroxyapatite. (See Col. 2, lines 44 - 46) Silver specifically teaches that the calcium phosphate is crystalline. (see Col. 2, lines 32 - 34)

Since the claimed invention is directed to a bioactive glass composite where the calcium and phosphorous molecular species are not crystalline, Silver cannot anticipate the claimed invention. Since Silver does not teach amorphous calcium and phosphate molecular species, it does not teach all elements of the claimed invention. Since Silver does not teach all elements of the claimed invention, it cannot anticipate the claimed invention and the Applicants respectfully request a withdrawal of the § 102 rejection and the allowance of the claims.

Claims Rejected under 35 U.S.C. § 103

Claims 11 – 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of U.S. Patent No. 5,532,217 to Silver et al. (hereafter Silver) in view of U. S. Patent No. 5,711,960 to Shikinami (hereinafter Shikinami). (Office Action dated 10-03-08, page 4) The claims are drawn to a biocompatible composite comprising a biocompatible polymer, bioactive glass in the form of fibers that act as a scaffold. (Office Action dated 10-03-08, page 4)

In making the rejection, the Examiner has stated

As discussed above the ‘217 patent discloses a biocompatible composite comprising bioactive glass and a biocompatible polymer, the reference however is silent to the spacing of the fibers and their proximity to each other. The orderly arrangement of the fibers is common in the art as shown in the ‘960 patent. The ‘960 patent discloses a biocompatible scaffold comprising a biocompatible polymer and bioactive glass on the surface of the fibers (abstract). The biocompatible polymers include polyethylene and poly-glycolic acid fibers (col. 10, line 50-61). With these things in mind it would have been obvious to arrange the fibers of the ‘217 patent as seen in the ‘960 patent in order to improve implant stability and compression properties for implantation. It would have been obvious to apply the fiber arrangement with an expected result of a stable implantable composite useful in bone repair treatments.

(Office Action dated 10-03-08, page 4)

The Supreme Court has recently reaffirmed the principle that “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the art.... This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *KSR Int’l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). The Court further stated that “[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). However, “the analysis need not seek out precise

teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” *Id.* And the Court expressly encouraged the use of common sense in such analysis. *Id.* Finally, the Court agreed that the teaching-suggestion-motivation test (“TSM test”) captured a helpful insight to prevent hindsight bias, but the Court held that “[h]elpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents.” *Id.*

As noted above, Silver does not teach a bioactive glass composite, comprising a biocompatible polymer, a bioactive glass including at least one calcium, and at least one phosphorous molecular species; wherein the calcium and said phosphorous molecular species are not crystalline.

Shikinami teaches an implant material which has high mechanical strength and durability in three-dimensional directions. (see Abstract) Shikinami teaches that the implant material functions to synchronize with the deformation characteristics of surrounding biological tissues and is capable of being penetrated by biological tissues into its fabric space. (see Abstract)

Shikinami teaches that the implant material uses as a base material, a biocompatible bulk structure of a three-dimensionally woven or knitted fabric of organic fibers or a composite fabric thereof, and its void ratio in the fabric is preferably set to 20 to 90 vol%. (see Abstract) The base material comprises a biocompatible bulk structure of a tri-axial or more three-dimensionally woven fabric of organic fibers, a tri-axial or more three-dimensionally knitted fabric of organic fibers or a combination thereof. (see Claim 1)

Shikinami in its Examples teaches the manufacturing of this three-dimensional woven fabric. Shikinami in Col. 7, line 25 through Col. 8, line 27 teaches how to manufacture a glass coated yarn. Only relevant portions of the disclosure of Shikinami are disclosed below to point out the differences between Shikinami and the claimed invention.

In its Example 1, Shikinami teaches that a high density polyethylene (HDPE) yarn of 50 denier filaments is coated with linear low-density polyethylene (LLDPE) (melted at 120°C), which is then subjected to a plasma treatment. (See Col. 17, lines 25 – 67)

Following the plasma treatment, the yarn of Shikanami is subjected to treatment in a phosphate solution and a calcium containing solution to produce a thin layer of calcium phosphate on the yarn. (See Col. 18, lines 1 – 7) The yarn is then used to produce a three-dimensional weave of a block shaped orthogonal fabric. (See Col. 18, lines 8 – 20) The weave is then placed in a mold and pressurized following, which it is coated with a fine particle powder of AW glass. (See Col. 18, lines 21 – 27)

Shikanami thus teaches manufacturing a weave from a yarn having a layer of calcium phosphate disposed on it with a layer of glass particles disposed upon the surface of the weave. Shikanami does not state that its calcium and phosphorus species are not crystalline as presently claimed. In fact, since the method disclosed by Shikanami in its examples is almost similar to that disclosed by Silver, one of ordinary skill in the art could assume that the calcium and phosphate species of Shikanami are crystalline. Shikanami thus does not rectify the deficiency of Silver.

Thus, Silver, **even when combined with** Shikanami would not produce the claimed invention. Since neither Silver nor Shikanami teach all elements of the claimed invention, there is no motivation to combine Silver with Shikanami.

In summary, the Applicants believe that the Examiner has not made a prima facie case of obviousness over Silver when combined with Shikanami. The Applicants therefore respectfully request a withdrawal of the obviousness rejection over Silver in view of Shikanami.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance is requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130 maintained by Assignee.

Respectfully submitted,

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